AUG 2 8 2003

BIONOSTICS

K032453

*510(k) Summary**

(a) (1) Submitter's name, address

Bionostics, Inc.
7 Jackson Road
Devens, MA 01432

Contact Person

Kathleen Storro
Sr. Director, QA & RA
(978) 772-7070 x 220

Date of preparation of this summary: 8 August 2003

(2) Device trade or proprietary name: Roche COMBITROL PLUS B and Roche AUTOTROL PLUS B Muti Analyte Controls

Device common or usual name or classification name:

Multi Analyte Control Solution, All Types (Assayed and Unassayed)

	CLASSIFICATION		
PRODUCT NOMENCLATURE	**NUMBER**	**CLASS**	**PANEL**
MULTI-ANALYTE CONTROLS – ALL KINDS	862.1660 75 JJY	I	CHEMISTRY

(3) Substantial Equivalence

This device is substantially equivalent in function, safety and efficacy to currently marketed devices produced by Bionostics. In example:

Comparison of COMBITROL PLUS B and AUTOTROL PLUS B to predicate devices for substantial equivalency

Characteristic		Predicate Devices	Modified Device
Name:	Blood Gas, Electrolyte and CO-Oximetry Control	Blood Gas, Electrolyte, Metabolite Control	Roche COMBITROL PLUS B and Roche AUTOTROL PLUS B
510(k), Date:	K913133, 09/27/1991	K972868, 08/28/1997	
Number of levels:	3	3	3
Analytes:	pH, blood gases, Na^+, K^+, Cl^-, iCa^{++}, tHb and Hb derivatives	pH, blood gases, Na^+, K^+, Li^+, Cl^-, iMg^{++}, iCa^{++}, Glucose, Lactate, BUN, Creatinine	pH, blood gases, Na^+, K^+, iCa^{++}, Cl^-, Li^+, iMg^{++}, Glucose, Lactate, BUN, Creatinine, tHb, Hb derivatives and bilirubin
Container:	Clear, glass ampoule	clear, glass ampoule	clear, glass ampoule
Fill volume:	2.5 mL	2.5 mL	1.7 mL
Color:	Red	Clear	Red
Matrix:	Buffered, aqueous electrolyte solution equilibrated with carbon dioxide and oxygen gas mixture.	Buffered, aqueous electrolyte solution equilibrated with carbon dioxide and oxygen gas mixture	Buffered, aqueous electrolyte solution equilibrated with carbon dioxide and oxygen gas mixture

* This summary of safety and effectiveness is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

(4) Description of the new device

COMBITROL PLUS B / AUTOTROL PLUS B is a specially formulated, three-level, aqueous liquid material intended for use to monitor all analytes measured by the Roche OMNI S Analyzer. **COMBITROL PLUS B / AUTOTROL PLUS B** provides a convenient method of performing periodic QC checks for laboratories selecting to measure liquid QC material as a part of their quality assurance program.

COMBITROL PLUS B / AUTOTROL PLUS B contains clinically relevant quantities of pH, PCO_2, PO_2, sodium, potassium, ionized calcium, chloride, glucose, lactate, urea, and hematocrit, and suitable concentrations of dyes to simulate clinically relevant values of bilirubin, hemoglobin and hemoglobin derivatives: O_2Hb, COHb, MetHb and HHb.

COMBITROL PLUS B / AUTOTROL PLUS B is a non-hazardous aqueous solution containing no biological materials.

(5) Intended use of the device

COMBITROL PLUS B / AUTOTROL PLUS B assayed controls are intended to be used to monitor and evaluate the analytical performance of the Roche OMNI S for analytes listed in the package insert.

(6) Technological characteristics of the device.

This material consists of buffered aqueous electrolyte solutions with clinically relevant concentrations of the targeted analytes, tonometered with precision gas mixtures of carbon dioxide and oxygen to achieve pH and blood gas values which span the range of values typical for such products with the same intended use. A mixture of dyes is used to simulate absorbance of hemoglobin derivatives and bilirubin. Hematocrit is simulated by conductivity.

(b) (1) Summary of non-clinical tests submitted with the premarket notification for the device.

Tests were conducted to verify specific performance requirements:
Real-time evaluation of products with essentially similar formulation and failure mode to support stability.
Test precision

(b) (2) Summary of clinical tests submitted with the premarket notification for the device.

N/A

(b) (3) Conclusions drawn from the clinical and non-clinical trials.

Comparison of technological characteristics, formulation and intended use to predicate devices listed in this summary support the claim of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 2 8 2003

Ms. Kathleen Storro
Senior Director, QA and Regulatory Affairs
Bionostics, Inc.
7 Jackson Road
Devens, MA 01432

Re: k032453
Trade/Device Name: Roche COMBITROL PLUS B and
Roche AUTOTROL PLUS B
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality Control Material (Assayed and Unassayed).
Regulatory Class: Class I
Product Code: JJY
Dated: August 8, 2003
Received: August 15, 2003

Dear Ms. Storro:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K03 2453

Device Name: Roche COMBITROL PLUS B and
Roche AUTOTROL PLUS B

Indications for Use:

COMBITROL PLUS B / AUTOTROL PLUS B assayed controls are intended to be used to monitor and evaluate the analytical performance of the Roche OMNI S for analytes listed in the package insert.

For *In Vitro* Diagnostic Use

Carol C Benson for Jean Cooper, DVM
Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K03 2453

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)